IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERZ PHARMACEUTICALS, LLC,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Merz Pharmaceuticals, LLC ("Merz"), by its undersigned attorneys, for its Complaint against defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Par"), alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Par's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Merz's CUVPOSA® drug product prior to the expiration of United States Patent Nos. 7,638,552 ("the '552 patent") and 7,816,396 (the "'396 patent") owned by Merz (collectively, "the patents-in-suit").

The Parties

2. Plaintiff Merz is a corporation organized and existing under the laws of the State of North Carolina, having a principal place of business at 4215 Tudor Lane, Greensboro, North Carolina 27410.

3. On information and belief, Defendant Par Pharmaceutical, Inc. is a corporation organized under the laws of Delaware, having a principal place of business at One Ram Ridge Road, Spring Valley, New York, 10977.

4. On information and belief, defendant Par Pharmaceutical Companies, Inc. is a corporation organized under the laws of Delaware, having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. On information and belief, Par Pharmaceutical Companies, Inc. is the parent company of Par Pharmaceutical, Inc.

5. On information and belief, Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. acted collaboratively in the preparation and submission of ANDA No. 204-438 to the FDA. On information and belief, Par Pharmaceutical, Inc.'s preparation and submission of ANDA No. 204-438 to the FDA was done at the direction, under the control, and for the direct benefit of Par Pharmaceutical Companies, Inc.

6. On information and belief, following any FDA approval of ANDA No. 204-438, Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 204-438 throughout the United States, and/or import such generic products into the United States.

7. On information and belief, Par has incorporated in the State of Delaware, and maintains a registered agent for service of process in Delaware. On information and belief, Par has regularly transacted business within this judicial district. Further, on information and belief, Par has developed numerous generic drugs for sale and use throughout the United States, including in this judicial district.

Jurisdiction and Venue

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over Par Pharmaceutical, Inc. because it is a corporation organized and existing under the laws of the State of Delaware and, by virtue of, *inter alia,* having availed itself of the rights and benefits of Delaware law, and having engaged in systematic and continuous contacts with the State of Delaware.

10. This Court has personal jurisdiction over Par Pharmaceutical Companies, Inc. because it is a corporation organized and existing under the laws of the State of Delaware and, by virtue of, *inter alia,* having availed itself of the rights and benefits of Delaware law, and having engaged in systematic and continuous contacts with the State of Delaware.

11. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patent-In-Suit

12. On December 29, 2009, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '552 patent, entitled "Method for Increasing the Bioavailability of Glycopyrrolate" to inventors Alan Roberts and Balaji Venkataraman. A copy of the '552 patent is attached hereto as Exhibit A.

13. On October 19, 2010, the USPTO duly and lawfully issued the '396 patent, entitled "Method for Increasing the Bioavailability of Glycopyrrolate" to inventors Alan Roberts and Balaji Venkataraman. A copy of the '396 patent is attached hereto as Exhibit B.

The CUVPOSA® Drug Product

14. Merz holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for glycopyrrolate oral solution (NDA No. 22-571), which it sells under the trade name CUVPOSA®. The claims of

the patents-in-suit cover, *inter alia*, methods of use and administration of glycopyrrolate or pharmaceutical compositions containing glycopyrrolate. Merz owns the '552 and '396 patents.

15. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '552 and '396 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to CUVPOSA®.

Acts Giving Rise to This Suit

16. Pursuant to Section 505 of the FFDCA, Par filed ANDA No. 204-438 ("Par's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of glycopyrrolate oral solution ("Par's Proposed Product"), before the expiration of the patents-in-suit.

17. In connection with the filing of its ANDA as described in the preceding paragraph, Par has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Par's ANDA.

18. No earlier than November 7, 2012, Par sent written notice of its ANDA certification to Merz ("Par's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Par's Notice Letter alleged that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Par's ANDA. Par's Notice Letter also informed Merz that Par seeks approval to market Par's Proposed Product before the patents-in-suit expire.

Count I: Infringement of the '552 Patent

19. Plaintiff repeats and realleges the allegations of paragraphs 1-18 as though fully set forth herein.

20. Par's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of glycopyrrolate oral solution, prior to the

expiration of the '552 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

21. There is a justiciable controversy between the parties hereto as to the infringement of the '552 patent.

22. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will infringe the '552 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Par's Proposed Product in the United States.

23. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will induce infringement of the '552 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Par's Proposed Product in the United States. On information and belief, upon FDA approval of Par's ANDA, Par will intentionally encourage acts of direct infringement with knowledge of the '552 patent and knowledge that its acts are encouraging infringement. On information and belief, through the product labeling for its Proposed Product, Par will intentionally encourage medical care workers and patients to administer Par's Proposed Product to patients to treat sialorrhea in a manner that infringes the '552 patent.

24. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will contributorily infringe the '552 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Par's Proposed Product in the United States. On information and belief, Par has had and continues to have knowledge that Par's Proposed Product is especially adapted for a use that infringes the '552 patent and that there is no substantial non-infringing use for Par's Proposed Product. On information and belief, the product labeling for Par's Proposed Product will instruct medical care workers and patients to administer Par's Proposed Product to patients to treat sialorrhea in a manner that is especially adapted to infringe the '552 patent.

25. Merz will be substantially and irreparably damaged and harmed if Par's infringement of the '552 patent is not enjoined.

26. Merz does not have an adequate remedy at law.

27. This case is an exceptional one, and Merz is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '396 Patent

28. Plaintiff repeats and realleges the allegations of paragraphs 1-27 as though fully set forth herein.

29. Par's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of glycopyrrolate oral solution, prior to the expiration of the '396 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

30. There is a justiciable controversy between the parties hereto as to the infringement of the '396 patent.

31. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will infringe the '396 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Par's Proposed Product in the United States.

32. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will induce infringement of the '396 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Par's Proposed Product in the United States. On information and belief, upon FDA approval of Par's ANDA, Par will intentionally encourage acts of direct infringement with knowledge of the '396 patent and knowledge that its acts are encouraging infringement. On information and belief, through the product labeling for its Proposed Product,

Par will intentionally encourage medical care workers and patients to administer Par's Proposed Product to patients to treat sialorrhea in a manner that infringes the '396 patent.

33. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will contributorily infringe the '396 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Par's Proposed Product in the United States. On information and belief, Par has had and continues to have knowledge that Par's Proposed Product is especially adapted for a use that infringes the '396 patent and that there is no substantial non-infringing use for Par's Proposed Product. On information and belief, the product labeling for Par's Proposed Product will instruct medical care workers and patients to administer Par's Proposed Product to patients to treat sialorrhea in a manner that is especially adapted to infringe the '396 patent.

34. Merz will be substantially and irreparably damaged and harmed if Par's infringement of the '396 patent is not enjoined.

35. Merz does not have an adequate remedy at law.

36. This case is an exceptional one, and Merz is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Merz respectfully requests the following relief:

(A) A Judgment be entered that Par has infringed the '552 and '396 patents by submitting ANDA No. 204-438;

(B) A Judgment be entered that Par has infringed, and that Par's making, using, selling, offering to sell, or importing Par's Proposed Product will infringe one or more claims of the '552 and '396 patents;

(C) An Order that the effective date of FDA approval of ANDA No. 204-438 be a date which is not earlier than the later of the expiration of the '552 and '396 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Par and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Par's Proposed Product until after the expiration of the '552 and '396 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Par, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods as claimed in the '552 and '396 patents, or from actively inducing or contributing to the infringement of any claim of the '552 and '396 patents, until after the expiration of the '552 and '396 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Par's Proposed Product will directly infringe, induce and/or contribute to infringement of the '552 and '396 patents;

(G) To the extent that Par has committed any acts with respect to the methods claimed in the '552 and '396 patents, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiff Merz be awarded damages for such acts;

(H) If Par engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Par's Proposed Product prior to the expiration of the '552 and '396 patents, a Judgment awarding damages to Plaintiff Merz resulting from such infringement, together with interest;

(I) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiff
Merz Pharmaceuticals, LLC

OF COUNSEL:

F. Dominic Cerrito
Eric C. Stops
Gabriel P. Brier
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

December 17, 2012
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